In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No.99-202V
September 17, 2007

LISA A. LIPPA,	*	
	*	
Petitioner,	*	
	*	
v.	*	Onset of neurologic symptoms
	*	four months after hepatitis B
SECRETARY OF THE DEPARTMENT OF	*	vaccination; Dr. Hyde not a
HEALTH AND HUMAN SERVICES,	*	credible witness in the past;
	*	Dr. Poser gives no basis for
Respondent.	*	his opinion

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition dated July 28, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine caused an unspecified adverse reaction.

FACTS

Lisa Lippa, petitioner, was born on February 28, 1959. P's Ex. A.

---

[1] Because this order contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

According to a record from Henderson County Health Department, Ms. Lippa received her first hepatitis B vaccination on November 10, 1995 and her second hepatitis B vaccination on December 8, 1995. P's Ex. C.

On April 12, 1996, petitioner saw her physician, Dr. Zenida Maddela, about a feeling of pins and needles in her left foot which had started the previous Sunday, putting onset at April 7, 1996 or four months after her second hepatitis B vaccination. P's Ex. B, p. 5. Dr. Maddela initially thought the symptoms were a circulation problem and referred petitioner to the Peripheral Vascular Laboratory in Evansville, IN. *Id.* Petitioner had a history of a fracture to her left foot in 1994 and had pain beginning in the area where the fracture site was. P's Ex. D. Petitioner was found to have a slightly cool temperature to touch on the left foot as compared to the right. The impression was essentially normal arterial examination of both lower extremities. *Id*.

On April 20, 1996, petitioner saw Dr. Pedro Dominguez. P's Ex. M, p. 166. Petitioner had had no significant problems with her head until she started developing numbness in the left foot sometime around Easter. *Id*. It started as a feeling of numbness in the foot and gradually crept up the leg and all the way up the body to the arm. *Id*. She had noticed that she seemed to limp a little bit on the left side. There were no problems as far as headaches or any other symptoms. *Id*. A motor examination revealed some mild weakness of the dorsiflexors and plantar flexors on the left foot. *Id*. There was some slightly diminished sensation in patchy areas in the left leg as compared to the right. P's Ex. M, p. 167. An MRI scan revealed a small lesion deep in the upper parietal area which measured 2 cm and seemed to enhance with contrast. *Id*. At that time, Dr. Dominguez believed it was a malignant tumor. *Id*.

On April 21, 1996, petitioner was admitted to Methodist Hospital in Henderson, Kentucky. P's Ex. E, p. 13. According to the medical history, petitioner was first seen on April 12, 1996, complaining of tingling and numbness in the left foot which had started six days prior. *Id*. She denied having any trauma. *Id*. According to her husband, she had been dizzy prior to this, but had no actual syncope. *Id*. Petitioner was noted to have decreased sensation to pinprick and light touch over the left foot and a slight difference in temperature of the lower extremities. *Id*. The left foot was colder as compared to the right foot with weak femoral pulses on the left side. Before she came back for followup, the numbness and tingling increased, involving not only the left foot, but the whole left lower extremity with progression towards the thoracic spine and occasionally involving the left upper extremity. *Id*. She had an MRI of the head which showed a 2-cm tumor over the parietal area on the right. *Id*. She was then admitted.

Dr. Satish Shah evaluated petitioner and noted that petitioner had enjoyed good health until Easter Sunday morning when she awoke with a weak feeling and paresthesia in the left foot. P's Ex. E, p. 20. She dragged her foot when walking. An MRI of the brain showed a 2-cm re-enhancing lesion at the cortical medullary junction in the right parietal area. She had no headaches, vomiting, or difficulty with speech or swallowing. *Id.* Petitioner had no hypertension, diabetes, or heart disease. Petitioner's medical history was notable for a cystectomy, cholecystectomy, hysterectomy, and D&Cs. *Id.* On physical examination, petitioner presented with left leg weakness and slightly tingly sensation in her left leg on pinprick exam. Her reflexes were hyperactive in her left leg as compared to her right leg. P's Ex. E, p. 21. A gall bladder ultrasound was unremarkable except for post-cholecystectomy. P's Ex. M, p. 164. A CT scan of the abdomen and pelvis revealed a small, rounded, low-density opacity in the right

lower pelvis measuring approximately 2 cm which may have been a right abnexal cyst. P's Ex. M, p. 165. Dr. Maddela's impression was brain tumor -- primary vs. metastatic-- with resulting weakness and paresthesia over the left lower extremity. P's Ex. E, p. 14.

On April 25, 1996, petitioner had a CT scan of her head done which showed a delayed enhancement of one cm lesion within the right parietal white matter. P's Ex. L, p. 152. There was surrounding white matter edema without remarkable midline shift or gross ventricular effacement. *Id*. The appearance was thought to be most compatible with underlying neoplasm, question low-grade glioma. *Id*. An inflammatory process or an abscess was thought to be another consideration. *Id*.

On April 25, 1996, petitioner saw Dr. Steven Kuric who was referred by Dr. Dominguez. P's Ex. M, p. 169. Petitioner denied any recent illness or infection. She also denied any headaches. *Id*. She was originally scheduled for possible craniotomy. However, the CT scan revealed the lesion to be about 1.2 cm in size and, therefore, the better option was a stereotactic biopsy. *Id*.

On April 29, 1996, petitioner was admitted to Deaconess Hospital. P's Ex. L, p. 80. There, petitioner underwent a brain biopsy. P's Ex. F, p. 23. The cytopathology interpretation notes that smears and cell blocks revealed degenerating cells and inflammation with macrophages suspicious for a demyelinating disorder. *Id*. Petitioner was discharged on April 30, 1996 with a final diagnosis of right parietal lesion, possible inflammatory change. P's Ex. L, p. 82. Dr. Steven Kuric noted that petitioner was first evaluated by Dr. Maddela when she was admitted the week before to Community Methodist Hospital. She was then evaluated by Dr. Dominguez and subsequently referred to Dr. Kuric. P's Ex. L, p. 84. Petitioner had presented

with symptoms of numbness on her left side beginning after Easter Sunday. P's Ex. L, p. 82. An MRI scan was done which showed a lesion in the right parietal area near the post central gyrus measuring about 2 ½ cm in diameter. *Id*. She underwent extensive metastatic work-up which was all negative including CT of the chest, abdomen, pelvis, IVP, barium enema, and mammogram studies. *Id*. HIV studies were negative. CBC was normal. Thyroid studies were normal. *Id*. She underwent a stereotactic biopsy of the right parietal lesion. *Id*. The preliminary report on the smear sections during surgery was that it did not appear to look like a tumor, but more of a change consistent with inflammation. *Id*. A CT scan on April 30, 1996 revealed minimal edema in the deep white matter of the right supraventricular cerebral hemisphere. P's Ex. L, p. 109. The site of the prior biopsy appeared less edematous than on the study of April 25, 1996. *Id*. The center of the area of edema demonstrated a very tiny punctate focus of increased density compatible with minimal hemorrhage. *Id*. Petitioner's case was then referred to the Mayo Clinic for consultation. P's Ex. L, p. 121.

On May 7, 1996, petitioner saw Dr. Kuric for suture removal. P's Ex. M, p. 168.

On May 9, 1996, Dr. Thomas Sebo of the Mayo Clinic stated in a letter to Dr. David Risner of Deaconess Hospital that he agreed with the diagnosis of demyelinating disease. P's Ex. F, p. 24. Special stains showed axons to be present and myelin to be entirely absent. No evidence of a neoplasm was noted. *Id*. On the same day, Dr. Kuric contacted petitioner to discuss the verbal report that the illness was consistent with a demyelinating disease. P's Ex. M, p. 168. Dr. Kuric told petitioner to discontinue taking Dilantin since she had had no evidence of seizures. She was also to reduce the Decadron dose. *Id*.

On May 16, 1996, petitioner went for a follow-up with Dr. Satish Shah. P's Ex. G, p. 27. The impression was a demyelinating disease. Petitioner continued to have paresthesia in the left leg. *Id*. She had no visual symptoms or difficulty with speech, swallowing, or imbalance. *Id*. She denied incoordination or bladder symptoms. Her fundi and cranial nerves were normal. She had no weakness and no loss of pinprick sensation. *Id*. Her reflexes were 2 plus symmetrically. Her gait was normal. *Id*.

On May 17, 1996, a brainstem auditory evoked response report found that petitioner had a normal BAER and no electrophysiological evidence of dysfunction in bilateral auditory pathways. P's Ex. G, p. 28. Also on May 17, 1996, petitioner took a visual evoked response test which noted normal visual evoked responses, and no electrophysiological evidence of dysfunction in bilateral anterior visual pathways. P's Ex. G, p. 29.

In a June 3, 1996 letter to Dr. Shah, Dr. Kuric states petitioner was experiencing a heavy sensation on her left side, especially on the left leg and a little bit in the left hand. P's Ex. M, p. 172. She had not noted any weakness, and her gait and balance were good. *Id.* She was able to walk very well in the office. *Id*. She also noted a tremor on both sides, more prominent on the left side, which had increased since she had been off the Decadron. *Id*.

On June 6, 1996, petitioner saw Dr. Shah for a follow-up visit. P's Ex. G, p. 27. Petitioner continued to have a feeling of numbness and heaviness in the left leg. *Id*. She was also getting tremulous in both upper extremities, the left worse than the right. *Id*. She reported no difficulty with her eyesight, speech, or swallowing. *Id*. She had no problem with balance. Her multiple sclerosis (MS) profile was negative. *Id*.

On June 10, 1996, petitioner had a cranial MRI with and without contrast. P's Ex. G, p. 32. The impression was an enhancing lesion involving the deep white matter tracts within the right parietal lobe, which had decreased in size since the previous exam date of April 20, 1996. *Id*. No additional non-enhancing or enhancing lesions were demonstrated through the white matter tracts. The findings were consistent with a demyelinating plaque. *Id*.

On June 20, 1996, petitioner underwent an MRI. P's Ex. O, p. 201. The impression was an enhancing lesion involving the deep white matter tracts within the right parietal lobe which had decreased in size since the previous exam date of 4/20/96. There were no additional non-enhancing or enhancing lesions demonstrated throughout the white matter tracts. The findings were consistent with a demyelinating plaque. *Id*.

On July 12, 1996, petitioner saw Dr. Kuric who noted weakness on both sides and trouble walking. She was placed on Decadron again. P's Ex. M, p. 173.

On July 23, 1996, petitioner saw Dr. Shah for a follow-up visit. P's Ex. G, p. 33. Petitioner continued to have numbness of the left calf. She was also experiencing leg cramps in the nighttime. *Id*. The tremor in her right hand was much better. A repeat MRI showed decrease in the size of the lesion and no other lesions detected. There were no oligoclonal bands on the spinal fluid analysis. *Id*. Petitioner's mentation and cranial nerves were normal. *Id*. Her reflexes were symmetrical, and she had no sensory loss to pinprick in all four extremities. Her gait was unremarkable. *Id*. Dr. Shah believed that she probably could have a demyelinating disease of MS. *Id*.

On October 1, 1996, petitioner saw Dr. Shah for a follow-up visit. P's Ex. G, p. 35. Since the end of the prior week, petitioner had been complaining of more weakness on the left

side of her body. *Id*. It was difficult for her to walk. She denied any numbness or visual symptoms. *Id*. During the day, she felt tired and draggy and sleepy. *Id*. She had no sensory loss to pinprick. Her reflexes were slightly increased in the left upper extremity, but were otherwise normal. *Id*. Her gait was normal. Dr. Shah's impression was a demyelinating disease. *Id*. A repeat MRI was ordered. Petitioner was advised to take steroids, but did not want them at that time. *Id*.

On October 5, 1996, petitioner saw Dr. Anthony Perkins for an MRI. P's Ex. O, p. 196. The impression was a one-cm ring-enhancing lesion in the right posterior parietal deep cerebral white matter with surrounding vasogenic edema/inflammation. A repeat MRI was recommended in three to four months. P's Ex. O, p. 197.

On October 8, 1996, petitioner saw Dr. Kuric. There are no notes for this visit. P's Ex. M, p. 173.

On October 22, 1996, petitioner saw Dr. Paul Moots at the Vanderbilt University Medical Center. P's Ex. Q, p. 483. Dr. Moots' impression was that petitioner had a solitary, enhancing, right parietal lesion responsible for symptoms of numbness and weakness of the left side of the body. P's Ex. Q, p. 485. Dr. Moots felt that neither by history, nor by MRI or other testing was there evidence for other lesions or immunological abnormalities supportive of the diagnosis of MS. *Id*. However, it did remain an important consideration. According to Dr. Moots, the possibility of a post-infectious or post-vaccinal inflammatory lesion was reasonable, although it was remarkable that the lesion had continued in a progressive nature months after initial treatment. *Id*. The picture clearly was not that of acute disseminated encephalomyelitits as a more classical post-vaccinal process. *Id*.

On November 4, 1996, petitioner's mother cancelled petitioner's appointment with Dr. Kuric scheduled for November 5, 1996 because she was going to University of Virginia for a second opinion. P's Ex. M, p. 173.

On November 5, 1996, petitioner saw Dr. Neal Kassell at the University of Virginia for a Lars Leksell Stereotaxic Frame/lumbar puncture. P's Ex. N, p. 175. The MRI showed that her lesion had changed and was no longer enhancing. *Id*. Its characteristics were most consistent with demyelinating disease and the Leskell frame was then removed and the biopsy aborted. Petitioner then underwent a lumbar puncture. *Id*. There were two white cells, one red cell, glucose of 109, and protein of 29. Seventeen percent of the white cells were lymphocytes, and 45 percent were monocytes. A neurology consultation was performed and petitioner was referred to a neurologist in Louisville, KY for presumed evaluation of new onset of MS. *Id*.

According to a January 7, 1997 letter from Dr. John Melton to Dr. Zenida Maddela, petitioner saw Dr. Melton on December 11, 1996 for an initial consultation. P's Ex. J, p. 68. Petitioner was status post two Hepatitis B shots "before all of this" in November of 1995. Petitioner had no history of hypertension, diabetes, cancer, MI, or CVS. *Id.* There was no family history of MS. P's Ex. J, p. 69. Dr. Melton's impression was MS. *Id*.

On January 14, 1997, petitioner had a follow-up visit with Dr. Melton. P's Ex. J, p. 67. According to Dr. Melton's letter to Dr. Maddela, petitioner had been off steroids for several months and felt as if she were doing okay. She telephoned after she had some recurrent panic attacks and became very anxious. *Id*. She had no paresthesias, paralysis, or any evidence of seizure activity. She was started on Buspar and felt it was helping. On exam, petitioner's cranial nerve and motor testing were normal and there was no definite pronator drift. *Id*. Her reflexes

were symmetrical with toes downgoing bilaterally. Dr. Melton's impression was a single exacerbation of MS. *Id*.

On January 25, 1997, petitioner had a brain MRI. P's Ex. J, p. 66. The impression was an enhancing mass in the periventricular white matter right parietal region, which had shown decrease in size since the prior examination. *Id.* A prior exam also demonstrated surrounding edema which was no longer evident. No new lesions had developed in the interval. *Id*. No specific diagnosis could be made regarding the etiology. P's Ex. J, p. 65.

On February 12, 1997, Dr. Melton sent a letter to Dr. Maddela regarding the MRI scan of January 25, 1997. P's Ex. J, p. 64. Dr. Melton noted that the abnormality in the right hemisphere had decreased in size significantly since her last exam of October 1996. *Id*. Dr. Melton also noted that petitioner was complaining of increased anxiety and had even had some agoraphobia. *Id*. She was temporarily placed on Buspar, but that was discontinued. Dr. Melton then prescribed Prozac for these symptoms. *Id*.

According to Dr. Melton's March 18, 1997 letter to Dr. Maddela, petitioner was seen on follow-up. P's Ex. J, p. 63. She was "still a little swimmy-headed," but the left arm numbness was better and the left leg numbness just "comes and goes." *Id*. She denied having significant panic feeling since being placed on Prozac. *Id.* Dr. Melton's impression was that petitioner suffered a single episode of right hemispheric demyelination, of which the exact cause may never be known. *Id*. Certainly it could be related to the vaccine that she had for hepatitis, and she was instructed not to take the scheduled third dose or any other vaccines for that matter. *Id*. Petitioner was to continue taking Prozac as it had been helpful in decreasing some of her panic attacks and overall anxiety. *Id*.

On June 19, 1997, petitioner was seen on follow-up by Dr. Melton. P's Ex. J, p. 61. Dr. Melton's impression was that petitioner's history was sounding more like MS than brain metastasis. *Id*.

On June 21, 1997, petitioner had a brain MRI done. P's Ex. P, p. 428. The findings were three separate enhancing masses including left hemisphere, posterior aspect of the lateral ventricle, the right hemisphere at the posterior aspect of the lateral ventricle and the left hemisphere in the left temporal region. *Id*. Dr. Curt Liebman was unable to suggest a specific diagnosis regarding etiology of the lesions. *Id*. Without additional medical history, he suspected metastatic disease. *Id*.

On July 17, 1997, petitioner had a brain MRI done. P's Ex. H, p. 37. The impression was a slight decrease in enhancement in the lesion adjacent to the posterior bodies of the right and left lateral ventricles. P's Ex. H, p. 38. There was a new modular lesion in the right parietal subcortical white matter which enhanced. *Id*. The findings were compatible with MS although atypical. Other possible etiologies included lymphoma or metastases. *Id*.

On July 22, 1997, Dr. Melton requested prior authorization for Copaxone from petitioner's insurance company to treat petitioner's MS. P's Ex. J, p. 58.

On October 1, 1997, petitioner saw Dr. James Esser for sinusitis. His impression was thickening of the nasal turbinates, ethmoid sinus disease, and deviation of the nasal septum to the left. P's Ex. O, p. 192.

On October 14, 1997, petitioner saw Dr. Dominguez. P's Ex. M, p. 155. Dr. Dominguez noted that petitioner had presented with a lesion in the right parietal area about a year ago. *Id*. Dr. Dominguez had seen her in April 1996 and referred her to Dr. Kuric. Dr. Kuric did a biopsy

of the lesion which came back as compatible with MS. *Id*. The slides were sent to the Mayo Clinic which also confirmed the diagnosis of MS. *Id*. Thereafter, she had an attempted biopsy at the University of Virginia, but when they repeated the studies on her the lesions were gone. *Id*. She had an MRI scan done a few months ago and it showed lesions on the opposite (left) side. Dr. Dominguez reviewed a recent MRI scan and noted that the abnormality was much more aggressive looking in the sense that there was a lot of swelling, a lot of edema, low density attenuation lesion deep in the parietal area, and enhancement around the periphery. *Id*. His impression was that it could be an inflammatory process or a remote possibility was primary malignant brain tumor. *Id*. A few days prior to October 14, 1997, she had been complaining of some numbness and weakness of the left upper extremity and thought initially that it was related to a possible sinus problem. She was in the process of being worked up for the numbness and weakness when she had a seizure. *Id*. This led to admission to Community Methodist Hospital on October 14, 1997. According to the history, prior to the October 14, 1997 admission, petitioner had diarrhea for three days resulting in weakness and dehydration as well as weakness of the left upper extremity. P's Ex. O, p. 213. This prompted her to seek medical consultation and she was advised hospitalization. *Id*. Upon arrival at the admissions office, petitioner had a seizure episode leading to admission in the Intensive Care Unit. *Id*. An MRI of the brain revealed mass effect right posterior parietal lobe with advancing rim of enhancement compared to the previous exam, as well as adjacent vasogenic edema and mass effect, midline shift and subfalcine herniation. P's Ex. O, p. 236. Central nervous system neoplasm was favored. The two left cerebral enhancing lesions were not demonstrated on this exam. *Id*. Dr. Dominguez

recommended that petitioner go back to Louisville since that was where her current doctor was located. P's Ex. M, p. 156.

On October 16, 1997, petitioner was admitted to Baptist Hospital East. P's Ex. I, p. 48. According to Dr. John Melton's notes, petitioner originally presented to his office approximately one and one-half years earlier with the diagnosis of MS. She had a ring-enhancing lesion in the right hemisphere which was biopsied in Evansville, Indiana, with results showing evidence of demyelinization only. *Id*. Over the last year or so, she had had evidence of right hemispheric dysfunction, which eventually resolved completely with follow-up MRI scan showing complete resolution of the right hemisphere ring-enhancing lesion. *Id*. Subsequent to this, a diagnosis of a single demyelinating event was made. There had been a history of a vaccination, and they queried whether that had been the precipitating factor. *Id*. Her spinal tap had been performed and showed no apparent evidence of IgG elevation or oligoclonal banding. Eventually, she had evidence of left hemisphere dysfunction with some degree of numbness and weakness on the right side of her body. *Id*. At that time, the presumptive diagnosis of MS was made. A repeat scan, however, in April showed evidence of resolution of the previously noted abnormalities, but there was evidence of a small ring-enhancing lesion in the right posterior hemispheric region, despite significant left body findings. *Id*. She was started on Copaxone over the last six weeks and was tolerating it quite well. Nonetheless, several weeks ago, she began to note some degree of tingling and numbness involving the left hand which eventually progressed to weakness involving the left side of the body. *Id*. She was seen by an ear, nose, and throat surgeon with a complaint of mild headache, and was given a course of Medrol dose pack which relieved the left-sided symptoms. Nonetheless, this past week, the weakness was worse with increasing

headache, and she eventually suffered a true grand-mal seizure. *Id*. According to her husband, prior to this in the days leading up to that seizure, she may have had some mild seizures in which she just acted funny and held her left hand funny. Petitioner was admitted to Community Methodist Hospital where she underwent a MRI scan showing a large ring-enhancing mass with significant edema in the right hemisphere, indicating probable progression from the abnormality which was noted in April of this year. *Id*. After being transferred to Baptist Hospital East, petitioner stated that she was nearly back to normal. She denied any significant headache, change in vision, or definite weakness/numbness at that time. *Id*.

Dr. Melton's impression was demyelination consistent with cavitary[2] MS. P's Ex. I, p. 49. The seizure was due to the size of this abnormality in the right hemisphere as well as the surrounding edema. *Id*.

On October 17, 1997, petitioner had an EEG. P's Ex. I, p. 47. The impression was a mildly abnormal. The subtle slowing seen in the right hemisphere might be consistent with some underlying focal cortical pathology. *Id*. This was a minor finding, and clinical correlation was recommended. There was no evidence to support epileptiform potential based upon this tracing. *Id*.

On October 21, 1997, petitioner underwent a cerebral anteriogram. P's Ex. I, p. 44. The impression was predominantly avascular area in the right parietal lobe with some deviation of the branches around this area and some mass effect on the right anterior and right middle cerebral arteries. P's Ex. I, p. 45. There was no evidence of tumor neovascularity on the exam. *Id*.

---

[2] Cavitary is "characterized by the presence of a cavity or cavities." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 311.

Petitioner was discharged on October 22, 1997. According to the discharge summary, petitioner had a previous history of right hemisphere ring-enhancing lesion, status post-biopsy showing demyelination only, and eventual resolution of the right hemisphere mass one and one-half years ago. P's Ex. I, p. 40. This was followed by several small enhancing lesions in the left hemisphere earlier this year, also now completely resolved status post-steroid therapy. *Id*. She had a follow-up MRI scan in April 1997 which showed a small ring-enhancing lesion in the right hemisphere. For the past several weeks, she had been having more trouble with her left side than normal. *Id*. She apparently suffered a grand mal seizure as witnessed by her husband. An MRI scan at Community Methodist Hospital revealed a large 4 cm ring-enhancing mass in the right parietal region. She was transferred to Baptist Hospital East for further work-up. *Id*. She was placed on high dose Decadron and showed dramatic improvement. Dr. Melton's discharge diagnosis was cavitary MS. *Id*.

On November 11, 1997, petitioner saw Dr. Anthony Perkins for an MRI. P's Ex. O, p. 188. His impression was that the degree of mass effect in the right posterior parietal region had dramatically diminished since the previous study. There was surrounding signal alteration on the T2 data set compatible with edema. The surrounding enhancement was more ill-defined although it appeared thickened in some areas measuring approximately 5 mm in thickness. *Id*. The area of central hyperintensity of T2 and central hypointensity on T1 was compatible with encephalomalacia. There was a left posterior parietal periventricular area of signal hyperintensity that was not present on the previous examination. *Id*.

On February 11, 1998, petitioner saw Dr. Melton for a follow-up. P's Ex. J, p. 55. Petitioner was "doing great" and complained only of a mild degree of dizziness. Her mental

status examination, cranial nerves, and motor, coordination, and gait testing were completely normal. *Id*. She had a very fine intention tremor, but there was no pronator drift and her reflexes were symmetrical. *Id*. Her diagnosis was that of MS with recurrent exacerbations associated with cavitary/tumefactive lesions. P's Ex. J, p. 56. She was stable and on Betaseron since November 1997. Her dizziness was not treated because it was a very mild complaint. *Id*.

On March 3, 1998, petitioner saw Dr. Warren. She underwent an EEG. Dr. Warren's impression was a normal EEG during wakefulness and Stage I sleep. P's Ex. O, p. 184.

According to a March 12, 1998 letter from Dr. Melton to Dr. Maddela, petitioner underwent an EEG read by Dr. Roderick Warren as normal. P's Ex. J, p. 52. There was no asymmetry of amplitude formation. *Id*. Petitioner was tapered off Dilantin which Dr. Melton believed was causing her elevated GGT. *Id*.

On September 2, 1998, Dr. Vincent Calabrese saw petitioner. P's Ex. K, p. 71. A neurologic examination revealed that petitioner's cranial nerves were within normal limits, and her motor examination was normal with no evidence of any weakness on either side. *Id*. Her deep tendon reflexes were normal bilaterally and her plantar reflexes were downgoing. There was a moderate postural tremor of her left and a very minimal amount of tremor on the right side which was also postural. *Id*. Her coordination was normal and her gait was normal. Sensory examination of pin, vibratory, and position sense were normal. P's Ex. K, p. 72. She did not have any symptoms at the time and her EDSS score was 0. She was to continue on Betaseron as well as Prozac. Petitioner was entered into the MS TRACK study. *Id*.

On September 11, 1998, petitioner had a brain MRI. The impression was an abnormal increased signal intensity in the parietal periventricular white matter bilaterally, right greater than left, without evidence of enhancement or mass effect. P's Ex. K, p. 74.

On December 10, 1998, petitioner visited Dr. Calabrese because of a one-week history of numbness on the right side of her face. Petitioner was also feeling very tired and had had little sleep because of an illness in her family. P's Ex. K, p. 78. She was taking Betaseron and Prozac. *Id*. On examination, her cranial nerves were normal. *Id*. There was no facial asymmetry. Sensory examination for touch, pin, and temperature were normal bilaterally. Petitioner did have mild slurring of her speech, and her test phrases were not entirely normal. *Id*. Her coordination was normal bilaterally, though her gait was a little bit unsteady. *Id*. Petitioner was having mild, mainly subjective symptoms on her face. *Id*. There symptoms were similar to what she had had prior to an attack, which was followed by a seizure. Therefore, Dr. Calabrese gave her an abbreviated course of oral prednisone. *Id*.

On March 10, 1999, petitioner saw Dr. Calabrese for a follow-up evaluation of her MS. P's Ex. U, p. 35[3]. Petitioner stated that the steroid helped with the December episode and that it cleared up after about a month. *Id.* Since then, she had experienced no new problems, but continued to have difficulty with fatigue. *Id.* She was also experiencing panic attacks, especially in large crowds.

On July 2, 1999, petitioner saw Dr. Calabrese for a follow-up regarding her MS. P's Ex. U, p. 31. She appeared to be very depressed. *Id*.

---

[3]Because the pages were not numbered, the undersigned has paginated Exhibits T, U, and V starting with page number 1 for each Exhibit.

On October 1, 1999, petitioner began to see Dr. Davenport rather than Dr. Calabrese. P's Ex. U, p. 27. On physical examination, petitioner had poorly palpable brachial artery reflexes bilaterally, but reasonably good radial artery pulses in both arms. Her gait and station were normal. *Id*. Romberg testing was negative at 10 seconds. *Id.* No tremors or dyskinesias were noted. She had normal symmetric strength about the head, face, upper extremities, and lower extremities. *Id*. Her reflexes were normal and symmetric except the knee jerks which were graded as +1 bilaterally. There was no optic disc pallor. Extraocular movements were normal in all directions. Her mood was good. *Id*.

On October 7, 1999, petitioner saw Dr. Davenport because she had been experiencing left leg and left arm numbness. P's Ex. U, p. 25. Dr. Davenport's impression was possible MS exacerbation. *Id*.

On November 15, 1999, petitioner saw Dr. Davenport for a follow-up of her MS. P's Ex. U, p. 3. She had been experiencing worsening lower extremity weakness over the weekend. She had some symptoms for the last few weeks and was treated with a course of IV Solu-Medrol. *Id*. Over the weekend, she became much weaker and had trouble walking. She also noticed some trouble controlling her bladder. Dr. Davenport's impression was MS exacerbation, most likely reflecting an upper thoracic myelopathy. *Id*.

Dr. Davenport saw petitioner for a follow-up on December 17, 1999. P's Ex. U, p. 6. His impression was MS with a recent exacerbation with a thoracic myelopathy, currently stable after a course of intravenous and oral steroids. *Id*.

On February 17, 2000, petitioner saw Dr. Davenport for a follow-up. P's Ex. U, p. 4. Dr. Davenport reported that petitioner had seen Dr. Charles Poser for evaluation in Boston in early

January. Dr. Poser felt that this was a post-vaccination encephalomyelitis. *Id*. Petitioner was not experiencing any recurrent neurologic symptoms, but was still bothered by a sense of burning from her waist down. *Id*. She did not want to take medicine for it. *Id*.

On March 27, 2000, petitioner saw Dr. Heidi Crayton at Georgetown University Medical Center for a neurologic evaluation. In a letter to Dr. Davenport, Dr. Crayton states that petitioner's history began April 10, 1996 when she awoke and felt that her left lower extremity was "asleep." P's Ex. T, p. 5. After about one week, she was seen by her physician. By April 19, 1996, the numbness/tingling had reached the level of her chest. The following day she was admitted to her local hospital for evaluation. *Id*. An MRI of her brain was read as a brain tumor. She had a brain biopsy and it came back as demyelination. *Id*. She was started on Decadron and Dilantin. Her numbness and tingling started to recede. *Id*. In October 1996, petitioner's foot started to turn inward and she experienced weakness of the left lower extremity. She was referred to Vanderbilt for a work-up which was negative. *Id*. In November 1996, she was seen at the University of Virginia. MRIs of her brain at that time had shown enlarging/receding lesions. She was due for another brain biopsy which was aborted secondary to a decrease in the size of her lesions. *Id*. She had a repeat spinal tap which was negative. She noted that she would continue to experience episodic numbness of the left face as well as numbness of her left hand. *Id*. Each time, she was treated with oral steroids and her symptoms would improve. *Id*. In September 1997, petitioner was started on Copaxone. P's Ex. T, p. 6. In October 1997, she started to experience headaches for one to two weeks. She thought they were secondary to sinus infections and was seen by an otolaryngologist who treated her with a Medrol dose pack. *Id*. Her headaches got much worse and her primary physician admitted her to the local hospital

where she was treated for dehydration. While in the ER waiting to be admitted, she experienced seizures. A brain MRI was significant for 4 cm brain-enhancing lesion on the right parietal lobe. *Id*. She was treated with five-days of IV methylprenisolone with resolution of symptoms. The seizure was thought to be secondary to Copaxone and, in November 1997, she was started on Betaseron. *Id*. In December 1998, petitioner experienced numbness of the right aspect of her face. She was treated with prednisone taper and had 100 percent recovery. In October 1999, she experienced fatigue. *Id*. She had low-dose Solu-Medrol for three days, without effect. The following month, she had bilateral lower extremity plegia. She also had burning of her lower extremities and a sensation of a tight band around her waist as well as urinary incontinence. *Id*. She was treated with four days of IV Solu-Medrol. The burning of her lower extremities persists as well as the urinary incontinence which is markedly improved. The tight band sensation around her waist is still present, but much improved. *Id*. She had marked improvement in her symptomology after one week. *Id.* Dr. Crayton notes that petitioner told her that she had had a hepatitis B vaccination on November 10, 1995 followed by the second vaccination December 8, 1995. P's Ex. T, p. 8. Petitioner believed her symptoms might be correlated somehow to her hepatitis vaccinations. Dr. Crayton told petitioner that she doubted that her neurological syndrome was related in any way to her vaccinations. *Id*. Dr. Crayton believed that petitioner's history was not classic for MS, but not inconsistent for MS. She believed that MS was the most likely diagnosis. *Id*.

OTHER SUBMITTED MATERIALS

Petitioner filed an affidavit on April 7, 1999. P's Ex. B, p. 4. She stated that prior to receiving the hepatitis B vaccinations in late 1995, petitioner led an active life and enjoyed a

number of activities. *Id*. In 1995, petitioner was working for the Henderson, Kentucky Public School System and was required to receive hepatitis B vaccine. *Id*. Petitioner states: "The first dose of the vaccine was administered to me on November 10, 1995 and the second dose on December 8, 1995. On the following Easter morning, April 7, 1996, I awoke with a feeling of pins and needles in my left foot." P's Ex. B, p. 5.

Petitioner submitted an expert report from Dr. Byron Hyde on August 15, 2000. Pet. Exp. Rep. Section 1, p. 4. Dr. Hyde's report states that after receiving the first vaccination of November 10, 1995, petitioner "experienced localized sore arm and some redness that lasted for 2-4 days." *Id*. This was followed by headaches which eventually resolved before she received the second vaccination. *Id*. The report further states that on December 8, 1995, petitioner received the second hepatitis B vaccination after which petitioner again experienced localized sore arm and some redness that lasted 2-4 days. *Id*. Dr. Hyde goes on to report that:

> At about the tenth day, she states that she started to experience severe frontal area headaches that were unlike any headache that she had ever had and these headaches persisted for a longer period than any headache that she had ever had. She felt she had to avoid light due to the headaches behind her eyes. This avoidance of light and persisting headaches continued for most of the week and she spent most of the time during this visit to her mother's home in the bedroom taking naps due to the severity of the symptoms. She was exhausted and had difficulty staying awake or keeping her eyes open. The severe headaches lasted for approximately one week or shortly longer and gradually got better until by the beginning of January the headaches were described as mild.

Id. at 4-5. By January, petitioner was better, but she noted that she was unable to stand without getting dizzy and would "wobble." *Id*. at 5. Her head was spinning. Her bowling scores went down. By March and April, she noted that she had numbness from the waist down which

gradually increased moving up to the left part of her torso. *Id*. Dr. Hyde believes that the hepatitis B vaccination caused petitioner's MS. *Id*. at 35. Presumably, the new symptoms closer in time to the hepatitis B vaccinations that Dr. Hyde recounts in his report come from petitioner when she saw Dr. Hyde in his office. They are nowhere in the medical records.

Petitioner also filed the expert report of Dr. Charles Poser. Pet. Exp. Rep. Section 3. Dr. Poser recounts that petitioner had no immediate reaction to the hepatitis B vaccination. *Id*. It was not until April 12, 1996 that petitioner experienced numbness of the left foot. *Id*. Dr. Poser states that in his opinion, "there is no question whatsoever that the original lesion and the resulting left sided symptoms were the direct result of the hepatitis vaccination." *Id*. He does not explain how a hepatitis B vaccination December 10, 1995 can cause MS four months later.

On November 21, 2000, respondent filed the expert reports of Dr. Burton Zweiman and Dr. Kottil Rammohan. Respondent's Ex. A and Ex. C. Both experts express concern regarding the diagnosis of MS in that several aspects of her illness are atypical of MS. *Id*. Drs. Zweiman and Rammohan also note that the history as recounted by Dr. Hyde is not reflected in the medical records or in petitioner's own sworn affidavit. Both doctors conclude that the hepatitis B vaccination had no role in petitioner's development of her illness. *Id*.

On June 13, 2001, respondent filed the expert report of Robert Fujinami, Ph.D. in which he responded to Dr. Hyde's report. R's Ex. G. Dr. Fujinami is the author of the article published in 1993 in the *Journal of Neuroimmunology* that petitioner's expert, Dr. Hyde cites to in his expert report. *Id*. Dr. Fujinami takes issue with the way in which Dr. Hyde described his work. He further states that after reviewing petitioner's medical records, the onset of her illness was

four months, and, therefore, "there is no temporal relationship between the hepatitis B virus vaccination and her first clinical episode." *Id*.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must offer "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, she would not have had MS (if that is what she had), but also that the vaccine was a substantial factor in bringing about her MS. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

This case was transferred to the undersigned on January 10, 2006. Also in January 2006, the undersigned was transferred the Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases such as Guillain-Barré syndrome, MS, transverse myelitis, and chronic inflammatory demyelinating polyneuropathy. The undersigned ruled in the four paradigm cases that hepatitis B vaccine could cause demyelinating diseases (GBS, MS, TM, and CIDP) if the onset of the disease occurred within three to 30 days post-vaccination based on the testimony of petitioner's Dr. Vera Byers and respondent's Dr. Roland Martin. The paradigm case dealing with MS was Werderitsh v. Secretary of HHS, No. 99-310V, 2006 WL 1672884, *18 (Fed. Cl. Spec. Mstr. May 26, 2006).

Here, petitioner's onset of MS, if she has MS, was four months post-hepatitis B vaccination number two. Her attempt to create symptoms closer in time to her second vaccination in the context of litigation is highly suspect. The undersigned must assume that during her visit to Dr. Byron Hyde, she informed him of rashes and headaches that appear nowhere in the medical records.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed.

Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

In addition, Dr. Hyde is a very poor witness with limited credibility. Respondent at Ex. L has filed the undersigned's opinion in Gardner-Cooke (which was affirmed), dismissing petitioner's case. Dr. Hyde has no medical specialty. He does not practice medicine for a living. He dabbles in vaccine cases. Former special master French also castigated Dr. Hyde in Doe v. Secretary of HHS, No. 99-670V, 2004 WL 3321302, at *28, *29, *30 (Fed. Cl. Spec. Mstr. Oct. 5, 2004), finding his credentials unpersuasive, especially compared to respondent's experts in that case, and his answers evasive.

Dr. Charles Poser, who is a neurologist, does not give any basis for his opinion that hepatitis B vaccine caused petitioner's atypical MS. He accepts the four-month onset. Under the Federal Circuit's rulings in Knudsen, Althen, and Capizzano, petitioner's expert must provide a biologically plausible medical theory connecting causally the vaccination and the illness, a logical sequence of cause and effect, and a medically appropriate timeframe between vaccination and onset. Dr. Poser says nothing about any of these three criteria. His opinion is conclusory.

Petitioner is ORDERED TO SHOW CAUSE by November 15, 2007 why this case should not be dismissed for failure to make a prima facie case.

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master